K022187
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SEP 2 4 2002

9 510(K) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and CFR 21 §807.92.

Submitter's Information:

Name:	RADI Medical Systems AB
Address:	Palmbladsgatan 10, SE-754 50 Uppsala, Sweden
Phone/Fax:	+46-18-161000 / +46-18-161099
Contact Person:	Mats Granlund
Date of Preparation:	July 2, 2002

Device Name:

Trade Names:	PressureWire™ Sensor
Common Name:	Pressure Guidewire
Classification Name:	Catheter Guide Wire (870.1330) Catheter Tip Pressure Transducer (870.2870) Thermodilution probe (870.1915)

Predicate Device Names: PressureWire™ Sensor (K002962)

FloWire Doppler Guide wire (K972762)

Device Description:
The PressureWire™ Sensor consists of a pressure and temperature sensitive sensor mounted on a steerable guidewire to perform real-time invasive physiological measurement in the circulatory system and a detachable cable for connection to a diagnostic computer of the manufacturer's. The detachable cable has an identification memory chip containing the individual calibration parameters for the sensor.

The guidewire has an outer diameter of .014" and comes in two lenghts 183 and 300 cm. The pressure sensor is mounted just proximal of the 3 cm shapeable radiopaque tip.

The signals from the sensor are used for calculation and presentation of any parameters and indices based on temperature and pressure, such as detection of small temperature differences and Fractional Flow Reserve (FFR). By also using the temperature sensitivity in the cables within the device also flow ratios such as Coronary Flow Reserve (CFR) could be derived.

Indication for Use:
PressureWire™ Sensor is indicated to direct a catheter through a blood vessel to measure physiological parameters in the coronary and peripheral blood vessels.

Technical Characteristics Summary:
The technical characteristics of PressureWire™ Sensor are identical with the predicate device (K002962) with the exception of a capacitor.

10 Description

The device is technically identical with the predicate with exception of the capacitor.

10.1 Intended Use

The signals from the sensor are used for calculation and presentation of any parameters and indices based on temperature and pressure, such as detection of small temperature differences and Fractional Flow Reserve (FFR). By also using the temperature sensitivity in the cables within the device also flow ratios such as Coronary Flow Reserve (CFR) could be derived. The calculation of the signals is made by the manufacturer's RADIAnalyzer™ (See concurrent 510(k) submission)

10.2 Indications for Use

The Pressure Wire Sensor is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the coronary and peripheral blood vessels.

10.3 Contraindications

Use of the PressureWire™ Sensor is contraindicated for use in the cerebral vasculature.

10.4 Principles of Operation

For measurements, the PressureWire™ Sensor is connected to the RADIAnalyzer™, which. After calibration of the sensor in saline solution the system is ready for use.

The mechanical principles of operation are the same as for any ordinary guidewire.

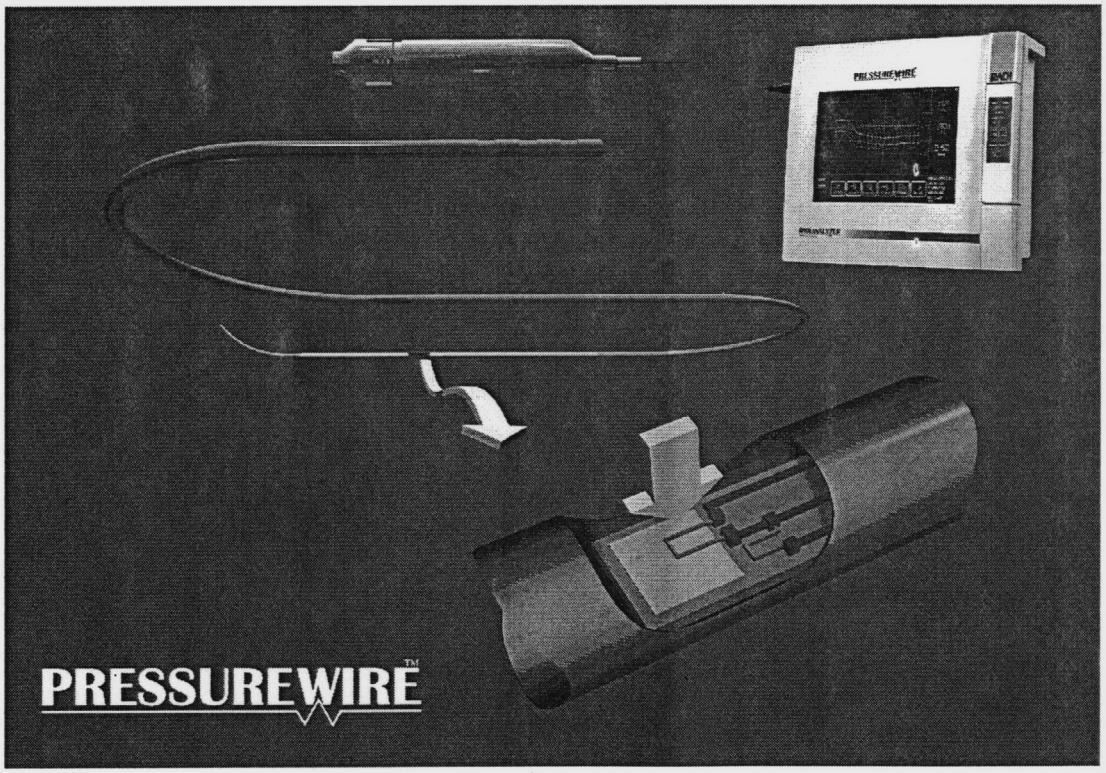


Figure 10.1 Pressure Wire Sensor connected to RADIAnalyzer

10.5 Composition and Physical Description

The PressureWire™ Sensor consists of three parts, the sensor, the guidewire, and the torque device. All parts are sterile and for single use only. No changes have been made in the composition apart from the incorporation of the capacitor, which is mounted at the circuit board with in the contact (G), see figure below.

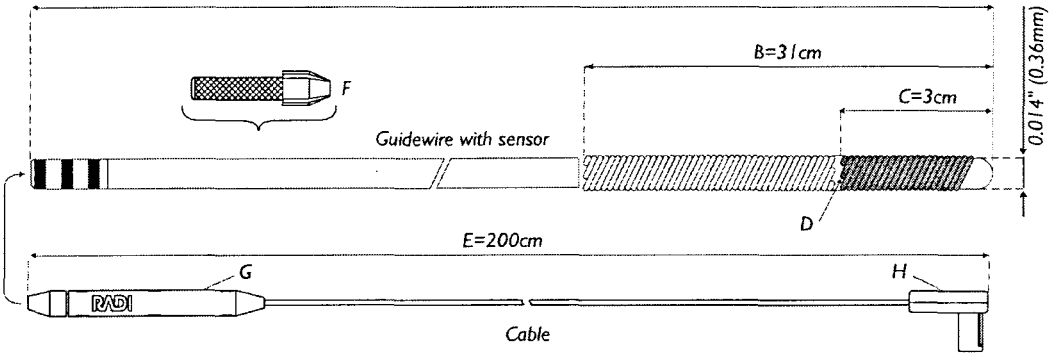


Figure 10.2: Device parts

The guidewire part is available in two lengths (183, 300 cm). The very tip consists of a 3 cm Pt coil distal of the sensor element, and proximal of the sensor element there is a 28 cm stainless steel coil followed by a PTFE coated stainless steel tube, which ends with the male contact. Within the tube and proximal coil there are mainly a core wire and a triple conductor (Micro Cable) for connection between the sensor element and the male contact. The actual sensor element is a piezo resistive pressure sensor coupled in a Wheatstone bridge. The linear working range for the pressure signals is from -30 to 300 mmHg, and for the temperature signals from 15 to 42°C.

The cable is identical with the predicate device with exception of the capacitor, which is incorporated in the connector (female contact) in parallel with a 100kOhm resistor to decrease the impedance of the shield (proximal tube) at high frequencies as well to increase the immunity of the sensor against disturbing signals from surrounding electrical equipment. To decrease the influence from surrounding electrical equipment has become of more importance when the temperature signals are actively used in the CFR calculations. The noise level has decreased tenfold with the incorporation of the capacitor.

(See Attachment III)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 2002

RADI Medical Systems AB
c/o Mr. Mats Granlund
Quality Manager
Palmbladsgatan 10
SE-754 50 Uppsala
Sweden

Re: K022187
Trade Name: PressureWire Sensor
Regulation Number: 21 CFR 870.2870 and 870.1915
Regulation Name: Catheter Tip Pressure Transducer and Thermodilution Probe
Regulatory Class: Class II (two)
Product Code: DXO and KRB
Dated: July 2, 2002
Received: July 5, 2002

Dear Mr. Granlund:

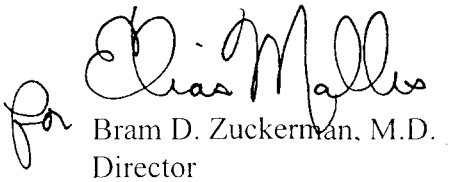
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2 Statement of Indications for Use

510(k) Number: K022187

Device Name: PressureWire™ Sensor

Indications for Use: The PressureWire™ Sensor is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the coronary and peripheral blood vessels

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

...ption Use Elias Malls
...CFR 801.109)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1/2/96)
